UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,716	11/10/2003	John Allen Robinson	AM100401	5638

25291 7590 08/06/2004

WYETH
PATENT LAW GROUP
5 GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
DESAI, ANAND U	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/705,716	ROBINSON ET AL.	
	Examiner	Art Unit	
	Anand U Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 November 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-88* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 13-33, 38-41 in part, drawn to an isolated nucleic acid fragment encoding a PAIGB polypeptide, a vector comprising the nucleic acid fragment, a transformed host cell, and a composition for regulating bone-forming activity comprising a nucleic acid fragment of claim 1, classified in class 435, subclass 69.1, 320.1, 325, 252.3, 254.2, and class 536, subclass 23.4.

II. Claims 8-12, 38-41 in part, 42, drawn to a polypeptide encoded by the isolated nucleic acid fragment, and a composition for regulating bone-forming activity comprising a polypeptide, classified in class 530, subclass 300, and 350.

III. Claim 34, drawn to a method of obtaining a nucleic acid fragment encoding the polypeptide, classified in class 436, subclass 94.

IV. Claim 35, drawn to a method of culturing and purifying a polypeptide, classified in class 435, subclass 71.1.

V. Claim 36, drawn to a method of detecting a nucleic acid fragment in a biological sample, classified in class 435, subclass 6.

VI. Claims 37, 38-41 in part, drawn to an antibody that binds PAIGB polypeptide, and a composition for regulating bone-forming activity comprising an antibody, classified in class 424, subclass 139.1.

VII. Claims 43 in part, 44, 48-50 in part, drawn to a polynucleotide agent that alters expression of PAIGB gene or polypeptide, classified in class 536, subclass 23.1.

VIII. Claims 43 in part, 45, 47, 48-50 in part, drawn to a polypeptide agent that alters expression of PAIGB gene or polypeptide, classified in class 514, subclass 2.

IX. Claims 43 in part, 46, 48-50 in part, drawn to a chemical small molecule agent that alters expression of PAIGB gene or polypeptide, classified in class 514, subclass 506.

X. Claims 51, and 52, drawn to a method for determining whether an agent alters the expression of PAIGB mRNA, classified in class 436, subclass 94.

XI. Claims 53, and 54, drawn to a method for screening agents for effectiveness in altering expression of a nucleic acid fragment, classified in class 435, subclass 91.1.

XII. Claims 55-58, drawn to a method of screening for agents useful for the treatment of bone related disorders, classified in class 424, subclass 572.

XIII. Claim 59, and 61, drawn to a method for evaluating the efficacy of a treatment of a bone related disorder, classified in class 424, subclass 549.

XIV. Claim 60, drawn to a method for identifying polypeptides capable of binding to PAIGB comprising applying a mammalian two-hybrid procedure, classified in class 435, subclass 7.8.

XV. Claims 62-79, drawn to a transgenic animal, classified in class 800, subclass 21.

XVI. Claims 80, 81, and 83-87, drawn to a method of studying bone mass determinants, a method of identifying an agent effective for the treatment of bone related disorders using transgenic animals, classified in class 800, subclass 3.

XVII. Claim 82, drawn to a method of studying the effect of PAIGB on bone disorders using transgenic animals, classified in class 800, subclass 25.

XVIII. Claim 88, drawn to a stably transfected cell line, classified in class 800, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I, II, VI, VII, VIII, IX and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The nucleic acids of Invention I are related to the protein of Invention II by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the claims of Invention I. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for processes other than the production of the protein, such as nucleic acid hybridization assay.

The proteins of Invention II are related to the antibodies of Invention VI by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct Inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The nucleic acid of Invention I and the antibody of Invention VI are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions.

The compositions of Inventions VII, VIII, IX, and XV are structurally different compositions with different modes of operation. Therefore, Inventions I, II, VI, VII, VIII, IX, and XV are distinct.

3. Inventions III, IV, V, X, XI, XII, XIII, XIV, XVI, XVII, and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods of use of compositions are not disclosed as capable of use together and they have different modes of operation, different functions, and different effects.

4. Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process

as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide product can be made by another and materially different process, such as by synthetic peptide synthesis.

5. Inventions I, II, VI, VII, VIII, IX, XV and III, IV, V, X, XI, XII, XIII, XIV, XVI, XVII, XVIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products of Inventions I, II, VI, VII, VIII, and IX can be used in the materially different processes of use of Inventions III, IV, V, X, XI, XII, XIII, and XIV. The transgenic animal of Invention XV can be used in the materially different processes of use of Inventions XVI, XVII, and XVIII.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

***
July 26, 2004

Jon P. Weber, Ph.D.
Primary Examiner